

Remarks

Claims 25 and 30-55 are pending in the subject application. By this Amendment, Applicants have canceled claims 33 and 46 and amended claims 25, 35, 42, and 47. Independent claims 25 and 42 have been amended to incorporate the elements of dependent claims 33 and 46, respectively. Claims 35 and 47 have been amended to correct dependency in view of the cancellation of claims 33 and 46. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 25, 30-32, 34-45, and 47-55 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 25, 33-42, and 46-53 are rejected under 35 USC §§102(a) and 102(e) as anticipated by Soos *et al.* (U.S. Patent No. 5,906,816) for the reasons set forth in the May 19, 2003 Office Action. In addition, claims 25, 30-37, and 39-55 are rejected under 35 USC §§102(a) and 102(e) as anticipated by Johnson *et al.* (U.S. Patent No. 5,939,286) for the reasons set forth in the May 19, 2003 Office Action. Applicants will assume for purposes of this Amendment that the Examiner meant to refer to the Office Action dated October 9, 2003, since the May 19 Office Action did not contain rejections under §102 based on the Soos *et al.* ('816) or the Johnson *et al.* ('286) patents. Applicants respectfully traverse these grounds of rejection.

Applicants respectfully maintain that the claimed invention is novel and nonobvious. The Examiner asserts that the Soos *et al.* ('816) patent teaches mammalian interferon tau and that it is useful for the treatment of autoimmune disease and that the Johnson *et al.* ('286) patent teaches interferon tau/interferon alpha chimeras and treatment of immune system disorders, including allergy, using the chimeras. Applicants respectfully maintain that the inhibition or suppression of allergen-specific IgE production or the proliferation of IgE-producing cells upon administration of interferon tau to a person was not inherent in the disclosure of the cited patents regarding treatment of patients with interferon tau. Under this rejection, the Examiner asserts that it is not necessary that an inherent property allegedly disclosed in a reference have been recognized by a person of ordinary skill in the art. Applicants respectfully assert that an ordinarily skilled artisan must recognize the presence of the inherent property. *In re Crown Operations International Ltd. v. Solutia Inc.*, 62 USPQ2d 1917, 1922 (Fed. Cir. 2002) ("If the . . . limitation is inherently disclosed by the [cited]

patent, it must be necessarily present and a person of ordinary skill in the art would recognize its presence.”). Applicants note that the *Scaltech* case referenced by Applicants and the Examiner dealt with anticipation by an on-sale bar under §102(b), not anticipation based on disclosure in U.S. patents under §102(a) and §102(e).

The Examiner also asserts under these rejections that “there is nothing in Applicants’ methods that differentiates them from what is taught by the prior art . . .” Applicants respectfully assert that the claimed methods are differentiated from the cited patents. Independent claims 25 and 42 recite “A method for suppressing or inhibiting allergen-specific IgE production . . .” and “A method for suppressing or inhibiting proliferation of an IgE-producing cell . . .”, respectively. There is nothing in the cited patents that teaches that interferon tau suppressed or inhibited allergen-specific IgE production or suppressed or inhibited proliferation of an IgE-producing cell. By this Amendment, Applicants have amended claims 25 and 42 to incorporate the elements of pending claims 33 and 46, respectively. Because the elements incorporated into claims 25 and 42 by amendment were present in pending dependent claims, Applicants respectfully submit that the amendments to the independent claims are proper and should be entered. If the Examiner does not enter the amendments, then Applicants respectfully assert that the remarks presented herein apply to dependent claims 33 and 46. Applicants respectfully assert that the preamble of claims 25 and 42 gives life and meaning to the claim language in claims 25 and 42 that reads administering “to a person or animal in need of suppression or inhibition of . . .” IgE production or proliferation of IgE-producing cells. The Court of Appeals for the Federal Circuit has held that a preamble of a claim can lend patentable weight where the preamble is necessary to give life, meaning, and vitality to the claim. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 51 USPQ2d 1162 (Fed. Cir. 1999). Thus, an element of Applicants’ claimed invention is recognition of a person or animal in need of suppression or inhibition of allergen-specific IgE production or proliferation of IgE producing cells. The claims of the subject application contain elements that are not taught or suggested, either literally or inherently, by the cited patents. As the Examiner is aware, in order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). The patents cited by the Examiner do not teach or suggest

recognition and treatment of a person in need of suppression or inhibition of allergen-specific IgE production (amended claim 25) or suppression or inhibition of proliferation of IgE-producing cells (amended claim 42).

Under these rejections, the Examiner also asserts that the patient population that would receive treatment with the claimed method “is not separate from the population treated by the methods of the ‘816 and ‘286 patents” and further asserts that the population of patients treated using the methods of the cited patents would “include a population suffering from IgE-related allergy . . .” Applicants respectfully assert that there is no evidence presented that the population of patients treated under the cited patents would include persons or animals in need of suppression or inhibition of IgE production or suppression or inhibition of proliferation of IgE-producing cells. Moreover, there are no results or findings presented in the cited patents to establish that interferon tau could be used to treat IgE-related allergies: the disclosure in the patents is clearly directed to the antiviral activity, the lack of cytotoxicity, and the use of interferon tau for treatment of autoimmune disorders, such as a multiple sclerosis (which is based on results showing the inhibition of development of experimental allergic encephalomyelitis in mice). While there is some data presented in the cited patents regarding antiproliferative effects of interferon tau, there is no teaching or suggestion of inhibition of proliferation of IgE-producing cells by interferon tau.

In regard to independent claims 54 and 55, Applicants note that these claims are only rejected under §102 based on the Soos *et al.* ('816) patent. In the October 9, 2003 Office Action, the Examiner asserted that Table 2 of the Soos *et al.* patent teaches *in vitro* administration of interferon tau and Applicants assume that this is the basis for the rejection of claims 54 and 55, although the Examiner did not specifically address these claims under the rejection in the outstanding Office Action. Applicants respectfully assert that there is no teaching or suggestion, literally or inherently, for the step of specifically contacting “a cell producing an allergen-specific IgE . . .” or contacting “an IgE producing cell” with an effective amount of interferon tau that is specifically recited in the claims. In order for there to be a teaching or suggestion of the contacting step in claims 54 and 55, a person of ordinary skill in the art would have to have known or had a reasonable expectation that interferon tau suppresses or inhibits allergen-specific IgE production or proliferation of an IgE producing cell. There is nothing in Table 2 or the cited patent to indicate that a cell producing an

allergen-specific IgE or a proliferating IgE-producing cell was contacted with interferon tau. Table 2 in the Soos *et al.* ('816) patent is directed to levels of cytotoxicity of interferons on cells and discloses nothing regarding actions of interferon tau on IgE producing cells or IgE responses. If the Examiner disagrees, then Applicants respectfully request the Examiner indicate where in the Soos *et al.* ('816) patent a cell producing an allergen-specific IgE or a proliferating IgE-producing cell is described and contacted with an interferon tau. Applicants respectfully assert that the Examiner has essentially acknowledged that the effect of interferon tau on allergen-specific IgE production and proliferation of IgE producing cells was not known or suggested prior to the filing of the subject application. Thus, the methods of claims 54 and 55 are novel and nonobvious. Moreover, a person of ordinary skill in the art would not have known what would constitute an "effective amount" of interferon tau for purposes of suppressing or inhibiting allergen-specific IgE production or suppressing or inhibiting proliferation of an IgE-producing cell since there was no teaching or suggestion of the activity recited in the claimed methods. Applicants also note that administering interferon tau to a patient as described in the cited patents would not necessarily result in contacting a cell producing an allergen-specific IgE or an IgE producing cell.

In view of the above remarks, reconsideration and withdrawal of the rejections under 35 USC §§102(a) and 102(e) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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